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Award Number: W81XWH-08-2-0168

TITLE: The relationship between statins and prostate cancer prevention

PRINCIPAL INVESTIGATOR: Wildon R. Farwell, M.D.

CONTRACTING ORGANIZATION: Brigham and Women's Hospital
Boston, MA 02130

REPORT DATE: September 2009

TYPE OF REPORT: Annual Summary

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT:

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REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
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1. REPORT DATE (DD-MM-YYYY) 01/09/2009		2. REPORT TYPE Annual Summary		3. DATES COVERED (From - To) 1 Sep 2008 – 31 Aug 2009	
4. TITLE AND SUBTITLE The relationship between statins and prostate cancer prevention				5a. CONTRACT NUMBER W81XWH-08-2-0168	
				5b. GRANT NUMBER	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Wildon R. Farwell, M.D. Email: wildon.farwell@va.gov				5d. PROJECT NUMBER PC073416	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Brigham and Women's Hospital Inc 75 Francis Street Research Administration Boston, MA 02115-6110				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research And Material Command Fort Detrick, MD 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for public release; distribution unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT Prostate cancer is the most frequently diagnosed cancer, excluding non-melanoma skin cancer, among men in the United States. Few risk factors and strategies for prostate cancer prevention are known. Some evidence suggests that statins, a class of medications that reduce cholesterol, may reduce the incidence and progression of prostate cancer. Dr. Farwell is obtaining training that will allow him to investigate the relationship between statins and prostate cancer incidence and progression. He has taken classes at the Harvard School of Public Health and is having regular meetings with researchers at the Brigham and Women's Hospital and the VA Boston Healthcare System. He is assembling datasets and writing research plans that will allow him to investigate the relationship between statins and prostate cancer incidence, grade, and progression. During the past year, Dr. Farwell has made substantive progress toward becoming an independent investigator in the field of prostate cancer prevention.					
15. SUBJECT TERMS Prostate Cancer; Statins; Epidemiology					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT UU	18. NUMBER OF PAGES 22	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U			19b. TELEPHONE NUMBER (include area code)

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Introduction

Prostate cancer is the most frequently diagnosed cancer, excluding non-melanoma skin cancer, in the United States. In 2009, it is estimated that 192,280 men will be diagnosed with prostate cancer and 27,360 men will die from prostate cancer (Jemal, 2009). Few prevention strategies for prostate cancer exist. HMG-CoA reductase inhibitors, statins, may prevent prostate cancer incidence and progression. We previously reported that statin users were 10% less likely to develop any prostate cancer compared to users of anti-hypertensive medications (Farwell, 2008). Other papers have reported that statin users are at decreased risk for any prostate cancer (Graaf, 2004) (Shannon, 2005) (Platz, 2006). However, these studies have primarily investigated the general relationship between statin use and total prostate cancer incidence and not the specific relationship between statin use and the grade of prostate cancer at diagnosis or prostate cancer progression. Therefore, we proposed to perform sophisticated analyses and for Dr. Farwell to obtain additional training at the Harvard School of Public Health that would enable him to examine the specific relationship between statins and prostate cancer among men with various levels of risk for prostate cancer. Our proposed studies will investigate the relationship between statin use and prostate cancer grade at diagnosis and prostate cancer progression using data from the Physicians' Health Study, VA New England Healthcare System, and the Early Stage Prostate Cancer Cohort study.

Body

Dr. Farwell re-enrolled in the Harvard School of Public Health and completed 2 courses in the first year of his Department of Defense Physician Research Training Award. One completed course titled, "BIO214: Principles of Clinical Trials" described the methodological elements necessary for a successful clinical trial. In this course, Dr. Farwell completed several homework projects and a final group project. A second completed course titled, "EPI213: Epidemiology of Cancer" described known genetic and environmental risk factors for common cancer including prostate cancer. In this course, Dr. Farwell also completed several homework projects and a final exam. Dr. Farwell obtained 5.0 credits for the completion of the 2 courses and a grade of "pass" in each course. After completing these courses, Dr. Farwell has obtained a better understanding of what is known in the field of cancer epidemiology and what needs to be investigated. He also learned the skills necessary to plan and coordinate a clinical trial on prostate cancer prevention. In his courses, Dr. Farwell also made personal connections with leaders in the fields of cancer epidemiology and clinical trial design and implementation.

Dr. Farwell has continued to meet regularly with researchers at both Brigham and Women's Hospital and the VA Boston Healthcare System. Dr. Farwell meets regularly with his primary mentor, J. Michael Gaziano, MD MPH. During these meetings, Drs. Farwell and Gaziano discuss current research findings and opportunities for new research. They both also attend regular research meetings at the VA Boston Healthcare System. These research meetings discuss current research projects in the VA Healthcare System. Dr. Farwell has continued to strengthen his research ties with the Massachusetts Veterans Epidemiology Research and Information Center at the VA Boston Healthcare System. He is working with several investigators such as Drs. Leonard D'Avolio, PhD, and Elizabeth V. Lawler, ScD MPH, on projects related to prostate cancer incidence and progression.

Dr. Farwell submitted a plan for analysis of data from the Physicians' Health Study (PHS) II. The analysis plan was accepted and Dr. Farwell received a dataset to analyze. The dataset that Dr. Farwell received contains data on 25,132 participants of the PHS II of whom 21,834 responded to the question

about current use of lipid modifying treatment. Among these men, 35.4% reported currently taking treatment and 64.6% reported not currently taking treatment. Prostate cancer was reported among 1513 men. Prostate cancer was reported among 6.3% of men who reported currently taking treatment and 7.3% of men who reported not currently taking treatment, p difference < 0.01 . Gleason score at diagnostic biopsy was available for 946 men with prostate cancer and was < 7 among 64.9% of men who reported currently taking treatment and 59.4% of men who reported not currently taking treatment, p difference = 0.11. Gleason score at prostatectomy was available for 312 men with prostate cancer and was < 7 for 49.1% of men who reported currently taking treatment and 49.0% of men who reported not currently taking treatment, p difference = 1.00.

Our results thus far from the PHS II suggest that taking lipid modifying treatment may be associated with decreased risk for prostate cancer incidence. Taking lipid modifying treatment may also be associated with decreased risk for being diagnosed with prostate cancer with a high Gleason score. However, we are still analyzing our data. It is too early for us to make any final conclusions about our findings. We are beginning to create Cox proportional hazard models that will test whether the possible relationship between lipid modifying treatment and decreased risk for prostate cancer incidence holds after controlling for age and other potential confounders. Also, we have relatively few cases of prostate cancer and prostate cancer reports with Gleason scores. Therefore, we are waiting for additional cases that will strengthen the power of our analysis.

We have also begun to plan work using data from the VA Boston Healthcare System and the Early Stage Prostate Cancer Cohort study. We will submit data analysis plans for these datasets and received IRB approvals of our analyses. In the VA New England Healthcare System, over 29,000 patients between October 1, 1997 and October 1, 2007 with an ICD-9 code for prostate cancer have been identified. Researchers at the Massachusetts Veterans Epidemiology Research and Information Center are in the process of cleaning this dataset to identify patients with biopsy proven prostate cancer and a Gleason score. Researchers are also in the process of cleaning baseline and follow-up variables from the Early Stage Prostate Cancer Cohort Study. Of the 1,038 participants in the Early Stage Prostate Cancer Cohort Study, 31.2% reported taking a statin at enrollment. Over 100 participants in the Early Stage Prostate Cancer Cohort study have died. Therefore, we should have the ability to investigate the relationship between statins and mortality among men diagnosed with early stage prostate cancer.

Key Research Accomplishments

- 1) Harvard School of Public Health
 - a) Completed re-enrollment process
 - b) 2008 – 2009
 - i) Completed BIO214, Principles of Clinical Trials
 - ii) Completed EPI213, Epidemiology of Cancer
 - c) 2009 – 2010
 - i) Reviewing course opportunities
- 2) Physicians' Health Study
 - a) Wrote analysis plan
 - b) Obtained dataset
 - c) Began analysis
- 3) VA New England Healthcare System
 - a) Planning study
- 4) Early Stage Prostate Cancer Cohort study
 - a) Planning study

Reportable Outcomes

Because the first year of the Physician Research Training Award was dedicated to Dr. Farwell taking classes at the Harvard School of Public Health and obtaining a dataset from the Physicians' Health Study, no abstracts, manuscripts, or grants that pertain to this grant have been completed at this time. We believe that this will change as additional work is performed and completed.

Conclusion

During the first year of the Physician Research Training Award, Dr. Farwell has learned about cancer epidemiology and clinical trial design and management that will enable him to be a leader in the research of prostate cancer prevention. He has received a dataset from the Physicians' Health Study and has begun to analyze the relationship between lipid modifying treatment and prostate cancer incidence. He has also begun to refine analysis plans for projects using data from the VA New England Healthcare System and Early Stage Prostate Cancer Cohort study. Dr. Farwell is well on his way to becoming an independent investigator with an emphasis in prostate cancer prevention.

Prostate cancer is commonly diagnosed and prevention strategies for prostate cancer incidence and progression are needed. Statins may be a safe and effective treatment for prostate cancer prevention. The results of our planned studies will contribute to whether statins should be further examined in clinical trials for prostate cancer prevention. The training that Dr. Farwell is obtaining from the Harvard School of Public Health will prepare him to be a leader in the field of prostate cancer prevention.

References

1. Jemal A, Siegel R, Ward E, Hao Y, Xu J, Thun M. Cancer statistics, 2009. *CA Cancer J Clin.* 2009;59:225-249.
2. Farwell WR, Scranton RE, Lawler EV, Lew RA, Brophy MT, Fiore LD, Gaziano JM. The association between statins and cancer incidence in a veterans population. *J Natl Cancer Inst.* 2008;100:134-139.
3. Graaf MR, Beiderbeck AB, Egberts AC, Richel DJ, Guchelaar HJ. The risk of cancer in users of statins. *J Clin Oncol.* 2004;22:2388-2394.
4. Shannon J, Tewoderos S, Garzotto M, Beer TM, Derenick R, Palma A, Farris PE. Statins and prostate cancer risk: a case-control study. *Am J Epidemiol.* 2005;162:318-325.
5. Platz EA, Leitzmann MF, Visvanathan K, et al. Statin drugs and risk of advanced prostate cancer. *J Natl Cancer Inst.* 2006; 98:1819-1825.

Appendix 1: CV of Dr. Wildon R. Farwell, MD MPH

**Harvard Medical School/Harvard School of Dental Medicine
Curriculum Vitae**

Date Prepared: 24 September 2009

Name: Wildon R. Farwell, MD MPH

Office Address: VA Boston Healthcare System
MAVERIC
150 S. Hunting Avenue
Boston, MA 02130

Brigham and Women's Hospital
Division of Aging
1620 Tremont Street
Boston, MA 02120

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BWH: wfarwell@partners.org

Work FAX: VA: 857-364-4424
BWH: 617-525-7739

Place of Birth: Springfield, MO; USA

Education

1996 BS		Biology	University of Missouri-Columbia, Columbia, MO
	(Magna cum laude)		
2000	MD	Medicine	University of Missouri-Columbia School of Medicine, Columbia, MO
2005	MPH	Clinical Effectiveness	Harvard School of Public Health, Boston, MA

Postdoctoral Training

7/2000 - 6/2003	Resident	Internal Medicine	Indiana University, Indianapolis, IN
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7/2003 - 6/2006	Fellow General	Internal Medicine	Harvard Medical School, Boston, MA
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Faculty Academic Appointments

2006 -	Instructor	Medicine	Harvard Medical School, Boston, MA
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Appointments at Hospitals/Affiliated Institutions

July, 2003 - 2007	Research Fellow	Medicine	VA Boston Healthcare System, Boston, MA
July, 2003 - 2007	Associate Physician	Medicine (Aging) Brigham	and Women's Hospital, Boston, MA
July, 2004 - 2007	Courtesy Medical Staff	Medicine	Faulkner Hospital, Boston, MA
July, 2007 -	Staff Physician	Medicine (General Medicine)	VA Boston Healthcare System, Boston, MA
July, 2007 -	Associate Epidemiologist	Medicine (Aging)	Brigham and Women's Hospital, Boston, MA

Major Administrative Leadership Positions

Local

2007 -	Associate Director, Harvard Medical School Fellowship in General Medicine and Primary Care at the VA Boston Healthcare System	VA Boston Healthcare System, Boston, MA
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Committee Service

Local

1998-2000	Admissions Committee	University of Missouri-Columbia, School of Medicine, Columbia, MO
1998-2000		Member
2007- 2007-	Institutional Review Board	VA Boston Healthcare System, Boston, MA
		Member

National and International

2003-2005	Residency Review Committee for Internal Medicine	Accreditation Council for Graduate Medical Education
2003-2005		Member

Professional Societies

2000-2003	American College of Physicians	Member President, Indiana Council of Associates
2002-2005-2006	Society of General Internal Medicine	Member Member, National Meeting Programming Committee
2006-2007		Member, Abstract Review Committee
2007-		Member, Finance Committee

Editorial Activities

Ad Hoc Reviewer, Archives of Internal Medicine

Other Editorial Roles

2009 -	Editorial Board	Open Journal of Oncology
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Honors and Prizes

1997	Student Leadership and Service Award	University of Missouri-Columbia, School of Medicine	
2000	Holt Leadership Award	University of Missouri-Columbia, School of Medicine	
2000 Comm	encement Speaker	University of Missouri-Columbia, School of Medicine	
2007	Joseph E. Johnson Leadership Award	American College of Physicians	This national award recognizes an Associate member of the College who has demonstrated qualities that exemplify the College's mission "to enhance the quality and effectiveness of health care by fostering excellence and professionalism in the practice of medicine."

Report of Funded and Unfunded Projects

Funding Information

Current

2008-2011	The Relationship between Statins and Prostate Cancer	
DoD,	PC073416	
PI,	\$390,000	
	The major goal of this study is to develop skills to be an independent successful researcher. The projects will investigate the relationship between medications to lower cholesterol and prostate cancer incidence and progression.	

2009 Carter Co-Investigator,	The Association between Statins and Melanoma Recurrence Foundation \$30,000
	The major goal of this study is to develop a cohort of patients with melanoma. The project will investigate the relationship between medications to lower cholesterol and melanoma incidence and progression.
2007-2009 NIH, Site-PI,	Testosterone Supplementation for Men with Sarcopenia U01AGO14369/CFDA \$100,000
	This randomized controlled clinical trial is designed to investigate whether testosterone gel can increase muscle strength among men with sarcopenia and low testosterone.
2007-2009 VA Site-PI,	VISN Collaborative for Improving Hypertension Management with ATHENA-HTN \$91,000
	This randomized controlled trial is designed to investigate whether a computerized tool will help primary care providers manage patients with hypertension.
2008-2013	The VA Keratinocyte Carcinoma Chemotherapy Trial VA, CSP 562 National Study Director, \$11,366,611
	This national randomized controlled clinical trial is designed to investigate whether topical 5-FU will prevent keratinocyte carcinoma (basal cell and squamous cell skin cancer). I oversee all administrative aspects of this national clinical trial.
2009 Merck, Site-PI,	The Study of Heart and Renal Protection MK-0653 \$30,000
	This international randomized controlled clinical trial is designed to investigate whether cholesterol lowering treatments reduce cardiovascular outcomes among patients with renal disease.
2009- VA Site-PI,	The Early Stage Prostate Cancer Cohort Study \$30,000
	This observational study is designed to observe men with early stage prostate cancer and investigate risk factors for prostate cancer progression.
2006-2009 Pharm Co-Investigator	Head and Neck Cancer Treatment in the Veterans Affairs (VA): Evaluation of Treatment Patterns, Outcomes, and Costs erit
	This pharmacoepidemiology project is designed to describe treatment patterns for patients with locoregionally advanced squamous cell cancer of the head and neck. I oversee the data collection and analysis and I wrote the paper reporting our findings.

Current Unfunded Projects

2008-2009 Co-Investigator; Racial and Ethnic Differences in the Relationship Between Vitamin D and Parathyroid Hormone in the National Health and Nutrition Examination Survey (NHANES)
I am a co-investigator on a paper reporting the relationship between vitamin D and

	parathyroid hormone by race/ethnicity.
2009	Co-Investigator; Duration of Visit and Quality of US Adult Primary Care Visits I am a co-investigator on a paper reporting results on an analysis of duration and quality of US adult primary care visits.
2009	PI; The Prevalence of Tinnitus and Patient Characteristics in the National Health and Nutrition Examination Survey I am the principal investigator on a project to describe the prevalence of tinnitus and characteristics of patients with tinnitus.

Report of Local Teaching and Training

Teaching of Students in Courses

2003	Clinical Epidemiology (AC701.0) 2 nd year medical students	Harvard Medical School, Boston, MA Tutor for a 2-hr session per week for 4 months
2004-2007	Preventive Medicine and Nutrition (PM711.0) 2 nd year medical students	Harvard Medical School, Boston, MA Tutor for a 2-hr session per week for 4 months
2004-2006	Epidemiology 242 MPH students	Harvard School of Public Health, Boston, MA Teaching Assistant for a 90 minute session per week for 4 months
2009	Measuring and Analyzing the Outcomes of Health Care (HPM 530) MPH students	Harvard School of Public Health, Boston, MA Lecturer for a 120 minute session

Clinical Supervisory and Training Responsibilities

2004-2005	Primary Care Clinic Preceptor	4 hours per week
2005	General Medicine Ward Attending	8 hours per day for 2 weeks per year
2006-	Adult Diagnostic Treatment Center Preceptor	8 hours per day for 2 months per year

Formal Teaching of Peers (e.g., CME and other continuing education courses)

2008	Screening for Prostate Cancer Single A Core Curriculum in Adult Primary Care Medicine, Boston University	Presentation Boston University School of Medicine, Boston, MA
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Local Invited Presentations

2007	PSA Testing for Prostate Cancer; Grand Rounds Department of Medicine, VA Boston Healthcare System, Boston, MA
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Report of Regional, National and International Invited Teaching and Presentations

Invited Presentations and Courses

Regional

- 2007 After a period of intense debate, are physicians ordering PSA tests more frequently? ;
Presenting author (selected abstract)
Boston, MA (Society of General Internal Medicine)
- 2008 Is High-Density-Lipoprotein Cholesterol Associated with Developing Prostate Cancer?;
Presenting author (selected abstract)
Boston, MA (Society of General Internal Medicine)
- 2008 Career Panel; Panelist (selected presenter)
Boston, MA (Society of General Internal Medicine)

National

- 2003 Resident's Perspective on Professionalism; Presenter
New Orleans, LA (Accreditation Council for Graduate Medical Education)
- 2004 Mistakes Residents Notice; Presenter
Chicago, IL (Accreditation Council for Graduate Medical Education)
- 2004 Student, Resident, and Fellow Career Development Workshop; Presenter
Chicago, IL (Society of General Internal Medicine)
- 2004 Making things simpler: can non-HDL predict MI as well as LDL-C?; Presenter
St. Louis, IL (Washington University)
- 2005 Making things simpler: can non-HDL predict MI as well as LDL-C?; Presenter
Pittsburgh, PA (University of Pittsburgh)
- 2007 The Relationship between Statins and Cancer Incidence in a Veterans Population;
Presenter
Huntington Beach, CA (Southwest Oncology Group, Melanoma Prevention Working Group)
- 2009 Pharmacoepidemiology in the VA and Beyond; Presenter (Selected Abstract)
Miami, FL (Society of General Internal Medicine)

Report of Clinical Activities and Innovations

Current Licensure and Certification

- 2000 Medical License
- 2004 American Board of Internal Medicine

Practice Activities

- July 2003 - Clinician Preventive Cardiology, VA 4 hours per week
June 2006 Boston Healthcare System,
Boston, MA

July 2006 - Clinician

Primary Care, VA Boston
Healthcare System, Boston,
MA

4 hours per week

Report of Education of Patients and Service to the Community

Activities

2009 American Friends of Kenya / Physician
I participated in a medical mission with a total of 5 physicians that saw over 900 patients in and around Nairobi, Kenya, over a period of 6 days.

Report of Scholarship

Publications

Peer reviewed publications in print or other media

Research Investigations

1. **Farwell W**, Simonyi A, Scott H, Zhang JP, Carruthers V, Madsen R, Johnson J, Sun GY. Effects of ischemic tolerance on mRNA levels of IP3RI, β -actin, and neuron-specific enolase in hippocampal CA1 area of the gerbil brain. *Neurochemical Research*. 1998;23(4): 539-42.
2. **Farwell WR**, Stump TE, Wang J, Tafesse E, L'Italien G, Tierney WM. Weight Gain and New Onset Diabetes Associated with Olanzapine and Risperidone. *JGIM*. 2004;19(12): 1200-5.
3. **Farwell WR**, Sesso HD, Buring JE, Gaziano JM. Non-high density lipoprotein cholesterol versus low density lipoprotein cholesterol as a risk factor for first nonfatal myocardial infarction. *Am J Cardiol* 2005;96(8):1129-1134.
4. Taylor EN, Forman JP, **Farwell WR**. Serum anion gap and blood pressure in the National Health and Nutrition Examination Survey. *Hypertension*. 2007;50:1-5.
5. **Farwell WR**, Linder JA, Jha AK. Trends in Prostate-Specific Antigen Testing From 1995 Through 2004. *Arch Intern Med*. 2007;167(22):2497-2502.
6. **Farwell WR**, Scranton RE, Lawler EV, Lew RA, Brophy MT, Fiore LD, Gaziano JM. The Association between Statins and Cancer Incidence in a Veterans Population. *J Natl Cancer Inst*. 2008;100:134-139.
7. **Farwell WR**, Gaziano JM, Norkus EP, Sesso HD. The relationship between total plasma carotenoids and risk factors for chronic disease among middle-aged and older men. *Br J Nutr*. 2008;12:1-7.

8. **Farwell WR**, Taylor EN. Serum Bicarbonate, Anion Gap, and Insulin Resistance in the National Health and Nutrition Examination Survey. *Diabet Med*. 2008;25:798-804.
9. Scranton RE, **Farwell WR**, Gaziano JM. Lack of cholesterol awareness among physicians who smoke. *Int J Environ Res Public Health*. 2009;6:635-642.
10. **Farwell WR**, Taylor EN. Serum Anion Gap, Bicarbonate, and Inflammatory Biomarkers in the National Health and Nutrition Examination Survey. *In Press*.
11. Hernandez RK, **Farwell WR**, Canton MD, Lawler EV. Cholinesterase inhibitors and incidence of bradycardia among dementia patients in the Veterans Affairs New England Healthcare System. *In Press*.
12. Chen LM, **Farwell WR**, Jha AK. Primary care visit duration and quality: does good care take longer? *In Press*.

Non-peer reviewed scientific or medical publications/materials in print or other media

Reviews

1. Rahilly CR, **Farwell WR**. Prevalence of smoking in the United States: a focus on age, sex, ethnicity, and geographic patterns. *Current Cardiovascular Risk Reports*. 2007;1(5):379-383.

Letter to the Editor

1. **Farwell WR**, Scranton RE, Lawler EV, Lew RA, Brophy MT, Fiore LD, Gaziano JM. Response: Re: The Association Between Statins and Cancer Incidence in a Veterans Population. *J Natl Cancer Inst*. 2008;100:973-974.

Abstracts, Poster Presentations and Exhibits Presented at Professional Meetings

1. **Farwell WR**, Sesso HD, Lew RA, Scranton RE, Gaziano JM. The Association Between Statins and Cancer Prevention in the Physicians' Health Study. Presented at the Society of General Internal Medicine New England Region and National Meetings, 2006 meetings
2. **Farwell WR**, Scranton RE, Lawler EV, Lew RA, Gaziano JM. Can Statins Prevent Lung Cancer? Presented at the Society of General Internal Medicine New England Region, 2007 meeting; Presented at the Society of General Internal Medicine, 2007 national meeting
3. **Farwell WR**, Scranton RE, Lawler EV, Lew RA, Gaziano JM. Can Statins Prevent Colorectal Cancer? Presented at the Society for Epidemiologic Research, 2007 national meeting
4. Scranton RE, **Farwell W**, Ezrokhi M, Gaziano JM, Cincotta AH. Quick release bromocriptine

(Cycloset TM) improves glycaemic control in patients with diabetes failing metformin/sulfonylurea combination therapy. Presented at the European Association for the Study of Diabetes, 2007 international meeting

5. **Farwell WR**, Sesso HD, Gaziano JM. Is high-density-lipoprotein cholesterol associated with the risk of developing prostate cancer? Presented at the Society of General Internal Medicine New England Region, 2008 meeting; Presented at the Society of General Internal Medicine, 2008 national meeting
6. **Farwell WR**, Lawler E, Boulanger L, Cincotta AH, Scranton RE. Assessment of safety for bromocriptine: comparisons of reporting systems and a retrospective cohort study. Presented at the International Society for Pharmacoeconomics and Outcome Research, 2008 international meeting
7. Lawler E, Chittamooru S, Botteman M, **Farwell W**. Locally Advanced Head and Neck Cancer Treatment Patterns. Presented at the American Academy of Otolaryngology - Head and Neck Surgery, 2008 national meeting
8. Clark AS, **Farwell WR**. Height and Breast Cancer Mortality. Presented at Boston University School of Medicine Research Day, May 2008

Narrative Report (limit to 500 words)

My primary research interests include clinical epidemiology and clinical trials emphasizing cancer and cardiovascular disease prevention. Approximately 75% of my time is devoted to research with the remaining 25% of my time split between clinical and administrative responsibilities. I am the national study director for CSP 562, “The VA Keratinocyte Carcinoma Chemoprevention Trial”. This national randomized controlled clinical trial will investigate the role of topical application of 5-fluorouracil (5-FU) in the prevention of surgery for keratinocyte carcinomas. I am also the local principal investigator for the ATHENA-HTN study at the VA Boston Healthcare System. This study is investigating a new computerized tool for helping primary care physicians manage the blood pressure of their patient’s with hypertension. I am also the local principal investigator for the TOM study at the VA Boston Healthcare System. This study is investigating the utility of testosterone in older men with sarcopenia. I am also the local principal investigator and the national project director for the Early Stage Prostate Cancer Cohort Study, an observational study investigating risk factors for prostate cancer progression.

As a recipient of the Department of Defense Physician Research Training Award, I am learning the skills necessary to become a successful researcher. I am an author on 10 peer-reviewed publications with several additional papers in various stages of development. I am a funded investigator on 8 grants. I am developing expertise in the epidemiology of cardiovascular disease and cancer prevention.

I also have a strong commitment to teaching and clinical care. I have been a small group co-tutor for Clinical Epidemiology (AC701.0) and Preventive Medicine and Nutrition (PM711.0) at the

Harvard Medical School. I have been a preceptor for the West Roxbury VA Internal Medicine Resident Clinic and have served as a teaching attending on the general internal medicine ward at the West Roxbury VA. Currently, I have a primary care clinic at the Jamaica Plain campus of the VA Boston Healthcare System. I am also an attending for the Ambulatory Diagnostic and Treatment Center where I serve as a teaching attending to medical students and internal medicine residents from Boston University School of Medicine.

Overall, I am a grant-supported physician researcher focusing on the areas of cardiovascular and cancer epidemiology. I have a national reputation for my research and I am developing the skills necessary to become internationally recognized while maintaining an active primary care practice and teaching medical student and internal medicine residents.

VA BOSTON HEALTHCARE SYSTEM

HUMAN STUDIES SUBCOMMITTEE (IRB)

REPORT OF COMMITTEE ACTION


Version December 1, 2004

Date of Action:	April 13, 2009
Principal Investigator:	Wildon Farwell, M.D., MPH
Title of Submission:	"The Relationship between Statins and Prostate Cancer Prevention"
Protocol Number:	IRB #2140
Type of Submission & Item Description:	Request for Continued Approval of Human Studies
Human Subject Enrollment:	Yes: No: X
Vulnerable Population:	Yes: No: X Category: Entire Study: Sub-Population:
X	APPROVED at IRB meeting
	APPROVED under procedures for administrative review by
	CHANGES REQUIRED: Based on Committee review, the changes or actions noted below are stipulated as required for approval. Compliance with these stipulations may be confirmed under Committee procedures for administrative review.
	DEFERRED: The item has been deferred pending changes or clarifications noted below. The proposal will be reconsidered at the next Committee meeting after the requested information or changes are submitted.
	DISAPPROVED: The proposal was disapproved for the reasons noted below. Please consult with the ACOS for Research or the Committee Chairperson before resubmitting.
	NOTED

Note: For 'Changes Required' and 'deferred', responses must be received from the principal investigator within 60 days. After 60 days a new submission and full review are required.

COMMENTS (2K):

1. The ISO certified that data security provisions for this protocol are appropriate and meet VA requirements for data security protection.
2. This data analysis study continues to meet the criteria for waiver of the requirement for informed consent under 38 CFR 16.116(d)
3. This data analysis study continues to meet the criteria for waiver of HIPAA authorization under 45 CFR 164.512(i)(2)
4. The IRB determined that no conflict of interest for the PI or any other study personnel that may influence the conduct of the research existed previously for this protocol or arose since the last continuing review.
5. This study has been designated as minimal risk and one year approval.
6. Approval dates: 4/13/09 – 4/12/10


Carole Palumbo, Ph.D.
 Chair, Human Studies Subcommittee

PROJECT/PROGRAM TITLE: Request for **Continued Approval** of Human Studies IRB #2140 "The Relationship between Statins and Prostate Cancer Prevention"

PRINCIPAL INVESTIGATOR:
Wildon Farwell, M.D., MPH

VAMC:
VA Boston Healthcare System

REVIEW DATE:
April 13, 2009

COMMITTEE FINDINGS:

1. The information given in the Informed Consent under the Description of Research by Investigator is complete, accurate, and understandable to a research subject or a surrogate who possesses standard reading and comprehension skills.

☐ YES
☐ NO
☒ ICF Waived
2. The informed consent is obtained by the principal investigator or a trained and supervised designate under suitable circumstances.

☐ YES
☐ NO
☒ ICF Waived
3. Every effort has been made to decrease risk to subject(s)?

☒ YES
☐ NO
4. The potential research benefits justify the risk to subject(s)?

☒ YES
☐ NO
5. If subject is incompetent and surrogate consent is obtained, have all of the following conditions been met; a) the research can't be done on competent subjects; b) there is no risk to the subject, or if risk exists the direct benefit to subject is substantially greater; c) if an incompetent subject resists, he will not have to participate; d) if there exists any question about the subject's competency, the basis for decision on competency has been fully described.

☐ YES
☐ NO
☒ ICF Waived
6. If the subject is paid the payment is reasonable and commensurate with the subject's contribution.

☐ YES
☐ NO
☒ Not enrolling
7. Members of minorities and women have been included in the study population whenever possible and scientifically desirable.

☐ YES
☐ NO
☒ Not enrolling
8. Comments: (Indicate if Expedited Review)
This study continues to meet the criteria for waiver of the requirement for informed consent. This study continues to meet the criteria for waiver of HIPAA authorization.

RECOMMENDATION: ☒ APPROVE ☐ DISAPPROVE / REVISE

SIGNATURE OF CHAIRMAN


Carole Palumbo, Ph.D., Chair, Human Studies Subcommittee

DATE:

April 13, 2009

Partners Research Management Conflicts of Interest Reporting Form

NOTE: Principal Investigators must complete all three sections of this form. All other personnel must only complete Sections I and III.

Name of Individual completing form: Wildon Farwell MD

Title of Grant: The Relationship Between Statins and Prostate Cancer

Principal Investigator on Grant: Wildon Farwell MD

SECTION I: REPORTING (All Individuals must complete Section I)

PLEASE CIRCLE ONE (Note carefully the criteria):

DO YOU (including your spouse and dependent children) have any Significant Financial Interests (i) that would reasonably appear to be affected by the research for which the funding is sought, or (ii) in or from entities whose financial interests would reasonably appear to be affected by the proposed research?

NO

YES

IF YOU ANSWERED NO, please sign the form below and return.

IF YOU ANSWERED YES, please describe the Significant Financial Interest ("SFI"):

- If your SFI is in an entity or entities, list names of entity/entities:

- Does the SFI in the entity consist of income (employment, consultant, honoraria, non-institutional royalty or other income that, in the aggregate, including that paid to your spouse and dependent children, exceeds \$10,000 per year)? Yes No
If Yes, describe:

- Does the SFI in the entity consist of equity (stock, including stock options or any other ownership interest)?
____ Yes ____ No
If Yes, describe:

- If your SFI is not in an entity (e.g. if it consists of privately owned intellectual property), describe the SFI:

- Please briefly explain the connection between your proposed research and the SFI you have listed above (i.e., why is this Significant Financial Interest reasonably likely to be affected by the research, or why is the entity in which you have the Financial Interest reasonably likely to be affected by the proposed research?). Use back of form or additional sheets, if needed.

Title of Grant: The Relationship between Statins and Prostate Cancer

SECTION II: LIST OF INDIVIDUALS (Only the Principal Investigator must complete Section II)

List all Individuals, that is, all key personnel (if applicable) plus *all other individuals who you have determined to be responsible for the design or reporting of the research, or to play any role in conducting the research such that they reasonably would be expected to influence its outcome* at a Partners HealthCare institution. Only list those Individuals who meet the above definition who are working on the project at or on behalf of a Partners HealthCare institution. Individuals working on the project as an employee of or for the benefit of a subcontractor to this project do not have to be listed here since they will be covered under the subcontractor's conflict of interest process.

Principal Investigators, please have each of these Individuals complete this disclosure form and return it to you or to Research Management for submission with the project proposal. **Research Management can not consider the disclosure process to be complete until it receives forms from all Individuals.**

Please list all PIs and
(if applicable) Key Personnel:

Wildon Farwell

Please list all others who meet the italicized
definition above
(if None, please state so below)

SECTION III: CERTIFICATION (all Individuals must complete Section III)

I certify that the information disclosed in this form is true and accurate to the best of my knowledge.

Wildon Farwell
Signed - Individual

9/24/2009
Date